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10/527,554	07/26/2005	Wolfram Eichner	14503-016US1 F63105PCUS	7146
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EXAMINER				
WHITE, EVERETT NMN				
ART UNIT		PAPER NUMBER		
1623				
NOTIFICATION DATE		DELIVERY MODE		
12/10/2008		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary

Application No.

10/527,554

Applicant(s)

EICHNER ET AL

Examiner

EVERETT WHITE

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 August 2008.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-16 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 11 March 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date See Continuation Sheet
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Inventor's Patent Application
6) ☐ Other: _____

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :12/26/2006, 9/26/2007, 4/28/2008, & 11/11/2008.

DETAILED ACTION

1. The amendment filed August 4, 2008 has been received, entered and carefully considered. The amendment affects the instant application accordingly:
 - (A) New Claim 16 have been added;
 - (B) Claims 1-15 have been amended;
 - (C) Comments regarding Office Action have been provided drawn to:
 - (I) objection to the brief description of the drawings, which has been withdrawn;
 - (II) objection to the drawing of Figure 3, which will be withdrawn upon completion;
 - (III) 112, 2nd paragraph rejections, which have been withdrawn in-part.
2. Claims 1-16 are pending in the case.

Foreign Priority Claimed

3. This application is a 371 of PCT/EP03/09750 International Filing Date: September 11, 2003 published in German, which claims foreign priority to Germany 10242076.9 under 35 U.S.C. 119(a)-(d). It is noted that PCT/EP03/09750 and Germany 10242076.9 (September 11, 2002) are in Germany, no translation into English.

Drawings

4. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "Fig. 3" has been used to designate both "NH₂ and CHO/COOH coupling reactions" and "SH coupling reactions". Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner,

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the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

5. The proposed drawing change of the labeling of "Fig. 3" to - - Fig. 3.1- - and - - Fig. 3.2 - - is acknowledged by the Examiner.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In Claim 11, the metes and bounds of the phrase "other types of clinically relevant reactions to immediate-type allergens" cannot be determined since the specify type of reactions to immediate-type allergens the claim is in reference to has not be disclosed.

8. Applicant's arguments filed August 4, 2008 have been fully considered but they are not persuasive. Applicants argue that "patients with other types of clinically relevant reactions to immediate-type allergens" is clearly disclosed to include, for example, people allergic to pollen, mites, mammalian hair, saliva, fungi, insects, foods, and natural rubber/latex and states that a person of skill in the art, reading Applicants' specification as of its priority date, would have understood the metes and bounds of claim 11. This argument is not persuasive since this language appears to include allergens that are beyond that which is supported by the instant specification.

Claim Rejections - 35 USC § 102

New Ground of Rejection

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1, 2, 6, 8-13 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Arison et al (US Patent No. 5,952,347).

Applicants claim a method for treatment of allergy by hyposensitization, comprising administering a conjugate of hydroxyalkylstarch and an allergen to an allergy sufferer, wherein at least one hydroxyalkylstarch is covalently coupled to the allergen.

The Arison et al patent discloses a quinoline leukotriene antagonists of formula I (see title and abstract) that may be bound covalently to a macromolecule which may be selected as hydroxyalkylstarch base ester (see column 3, 5th paragraph), wherein the compounds may be used in a method for the treatment of asthma and allergies (see column 2, 4th paragraph). The Arison et al patent discloses pharmaceutical compositions comprising the compounds as being suitable via various administrations, which include oral and subcutaneous administrations (see column 5, lines 48 and 49), which anticipate the subcutaneously and orally administration recited in instant Claim 12. The description of treating asthma and allergies of the Arison et al patent anticipates the instantly claimed method for treatment of allergy comprising administering a conjugate of hydroxyalkylstarch and an allergen to an allergy sufferer.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
12. Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arison et al (US Patent No. 5,952,347) in view of Sommermeyer et al (US Patent No. 5,218,108).

Applicants claim a method for treatment of allergy by hyposensitization, comprising administering a conjugate of hydroxyalkylstarch and an allergen to an allergy sufferer, wherein at least one hydroxyalkylstarch is covalently coupled to the allergen.

The Arison et al patent discloses a quinoline leukotriene antagonists of formula I (see title and abstract) that may be bound covalently to a macromolecule which may be selected as hydroxyalkylstarch base ester (see column 3, 5th paragraph), wherein the compounds may be used in a method for the treatment of asthma and allergies (see column 2, 4th paragraph). The Arison et al patent discloses pharmaceutical compositions comprising the compounds as being suitable via various administrations, which include oral and subcutaneous administrations (see column 5, lines 48 and 49), which embraces the subcutaneously and orally administration recited in instant Claim 12.

The instantly claimed method for treatment of allergy by hyposensitization differs from the description of treating asthma and allergies of the Arison et al patent by further

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specifying the type of hydroxyalkylstarch and the properties of the starch that include molecular weight, molar substitution and the C2:C6 substitution ratio.

The Sommermeyer et al patent shows that the cited claimed properties of the hydroxyalkylstarch are well known in the art. The Sommermeyer et al patent discloses hydroxyethyl starches having a mean molecular weight of 60,000 – 600,000, a substitution degree MS of 0.15 – 0.5, and a ratio of the substitution of C2 to the substitution of C6 of the anhydroglucose units from 8 to 20, which covers the same properties recited for the hydroxyalkylstarch in instant Claims 3-5 and 16.

One of ordinary skill in this art would be motivated to combine the teaching of the Arison et al patent with the teaching of the Sommermeyer et al patent since both patents discloses therapeutic applications for hydroxyalkylstarches.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the hydroxyalkylstarch used in the method to treat asthma and allergies of the Arison et al patent with a hydroxyethylstarch having specific molecular weight and substitution properties in view of the recognition in the art, as evidenced by the Sommermeyer et al patent, that the hydroxyethyl starch having the specified properties can be completely broken down within a physiologically reasonable time.

13. Applicant's arguments with respect to Claims 1-16 have been considered but are moot in view of the new ground(s) of rejection.

Summary

14. All the pending claims (Claims 1-16) are rejected.
- 15.

Conclusion

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Examiner's Telephone Number, Fax Number, and Other Information

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to EVERETT WHITE whose telephone number is (571)272-0660. The examiner can normally be reached on 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-066127. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Everett White/
Examiner
Art Unit 1623

/Shaojia Anna Jiang/
Supervisory Patent Examiner, Art Unit 1623